Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Charles P. Kocoras	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	98 C 3952	DATE	7/16/2002
CASE TITLE	SmithKline Beecham vs. Apotex		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] **ENTER MEMORANDUM OPINION:** SmithKline's second and third motions in limine are granted. Their fourth motion in limine is denied. TorPharm's third motion (Doc 243-1) in limine is granted. Their first (Doc 239-1) is granted in part and denied in part, and the fifth (Doc 247-1) is denied. All remaining motions in limine will be decided at time of trial.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices
	No notices required.		
	Notices mailed by judge's staff.		JUL 17 2002 date docketed
	Notified counsel by telephone.		
✓	Docketing to mail notices.		SB docketing deputy initials
	Mail AO 450 form.		
	Copy to judge/magistrate judge.		date mailed notice
SCT	courtroom deputy's initials	U.S. DISTRICT COURT CLERK 02 JUL 16 AM 8:35 FILED-ED 10 Date/time received in central Clerk's Office	mailing deputy initials

Document Number

279

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

SMITHKLINE BEECHAM CORPORATION and BEECHAM GROUP, p.l.c.,	)	DOCKETED JUL 17 2002
Plaintiffs,	)	
vs.	)	98 C 3952
APOTEX CORP., APOTEX, INC., and TORPHARM, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION

CHARLES P. KOCORAS, Chief Judge:

Plaintiffs SmithKline Beecham Corporation and Beecham Group ("SmithKline") have filed four motions in limine; Defendants Apotex Corp., Apotex, Inc., and TorPharm, Inc. ("TorPharm") have filed seven. Decision of SmithKline's first motion in limine and TorPharm's second, fourth, sixth, and seventh motions is deferred until the time of trial, when we will entertain brief oral argument.

In their second motion in limine, SmithKline wishes to prevent TorPharm from introducing evidence bearing on the issue of invalidation of U.S. Letters Patent No. 4,721,723 ("the '723 patent") by public use. The motion encompasses testimony by Dr. William Wolf on that subject, both directly and for rebuttal of testimony pertaining to patient use. Our November 30 opinion granted SmithKline summary judgment that the '723 patent was not invalid because of public use, obviating further attention to that issue at trial. TorPharm's opposition to the motion rests on the premise that we would

279

reconsider our prior ruling. In light of the fact that we have declined to do so, SmithKline's argument that evidence bearing on the issue of public use, including Dr. Wolf's direct testimony, has no further purpose or place in this litigation. For reasons stated below, the testimony of Dr. Wolf will also be unnecessary for rebuttal of SmithKline's patient use evidence, so the second motion in limine is granted in its entirety.

SmithKline's third motion in limine revolves around TorPharm's efforts to invalidate the '723 patent under 35 U.S.C. § 112. Although TorPharm casts its argument in terms of § 112, this is nothing more than an effort to force SmithKline to use only the tests specifically enumerated in the language of the '723 patent to show the presence of infringing material within TorPharm's proposed product. Because our prior opinion already held that SmithKline is not so constrained, TorPharm's latest variation on this theme is just as unavailing as previous endeavors. Accordingly, SmithKline's motion to preclude TorPharm from advancing evidence of invalidation under § 112 is granted.

SmithKline's fourth motion in limine and TorPharm's third motion in limine are flip sides of the same coin. Both center on whether SmithKline can adduce evidence of the amount of hemihydrate present in TorPharm's product after it is marketed. TorPharm insists that we have already decided this issue in their favor, whereas SmithKline contends that no legal authority exists for the proposition that in cases brought under 35 U.S.C. § 271(e)(2)(A), an infringement analysis must focus on the state of the product at the time it is sold. On this issue, TorPharm has the better of this

argument. The Federal Circuit has explicitly stated that "[w]hat is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997); see also Bayer AG v. Biovail Corp., 279 F.3d 1340, 1346 (Fed. Cir. 2002); Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000); Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp., 146 F. Supp. 2d 572, 579-80 (D.N.J. 2001). The Glaxo court went on to note the importance of this time limitation in cases involving compounds that are capable of existing in various forms, such as the paroxetine hydrochloride at issue here. Glaxo, 110 F.3d at 1568. Changes that may occur in a product because of events that occur after the product is sold have no effect on the question of whether the "hypothetical" product at issue in an ANDA case will infringe at the time of sale, although they could come into play in deciding whether an actual commercial product infringes under § 271(a), a section not implicated in this case. See Bayer, 279 F.3d at 1350 ("infringement under § 271(e)(2)(A) by submission of an ANDA is not synonymous with infringement under § 271(a) by a commercial product").

SmithKline principally relies on Bayer AG v. Biovail Corp. to support its position that postsale events are fair game in an ANDA infringement action. 279 F.3d 1340. However, their reading of Bayer is much too expansive; in that case, the Federal Circuit held only that measurements taken both before and after manufacture of tablets were relevant to a § 271(e)(2)(A) analysis. Both of these events, however, take place *before* the product is marketed, and the Bayer court specifically stated that the inquiry

must look to what will likely be marketed under the ANDA. Bayer, 279 F.3d at 1346; see also id. at 1349 (stating that measurements of actual materials, rather than what is described in the ANDA, is "at best, only tangentially relevant to an ANDA infringement analysis"). Other cases to which SmithKline points are inapposite in that they focus on actual infringement or other patent-related issues, not the hypothetical scenario created by an ANDA submission. See, e.g., Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997); Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418 (Fed. Cir. 1994). Furthermore, SmithKline's theory of inducement to infringe emerges from cases that involved patents claiming particular uses of a drug. The ANDAs filed in those cases did not include the claimed uses, but the drugs would be prescribed by physicians for the uses disclaimed by the ANDA and claimed by the patent. See Bristol-Myers Squibb Co. v. Immunex Corp., 86 F. Supp. 2d 447 (D.N.J. 2000); Warner-Lambert Co. v. Apotex Corp. 1999 WL 259946, at *3 (N.D. Ill. Apr. 8, 1999). The courts faced with such situations held that the ANDA filer could be held liable for inducing the physicians to put the drugs to uses not covered by the ANDA and explicitly claimed in the preexisting patents. The fact that those plaintiffs could proceed on an inducement theory does not make such a claim viable here; those cases are clearly factually distinguishable from the instant case. As such, they do not impact our conclusion that patient use evidence, because it involves changes to the state of the paroxetine hydrochloride after the product is sold, is not relevant to the question of whether the proposed compound will contain infringing material at the time it is sold.

Consequently, TorPharm's motion to exclude this evidence is granted and SmithKline's motion to admit it is denied.

TorPharm's first motion in limine is related to the preceding discussion; they seek to prevent SmithKline from offering data obtained from expired tablets, tablets made from processes other than those given in the ANDA, and tablets made by its affiliates that will not be sold in the United States. For the reasons stated above, we agree that evidence derived from expired tablets is not relevant to the question of what will be sold. However, the latter two categories of evidence could bear on the qualities of the product TorPharm will ultimately market, and we are not limited to the four corners of the ANDA in making that determination. See Bayer, 212 F.3d at 1248-49; Glaxo, 110 F.3d at 1568; Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 2002 WL 449012, at *2. The motion is therefore granted with respect to tablets that have expired but otherwise denied.

Finally, TorPharm's fifth motion in limine attempts to preclude SmithKline from introducing any evidence derived from the commercial embodiment of the subject matter of the '723 patent. TorPharm is correct that an allegedly infringing product must be compared only to the claims of the patent, not the commercial embodiment manufactured by the patentee. See Glaxo Group, Ltd. v. TorPharm, Inc., 153 F.3d 1366, 1373 (Fed. Cir. 1998); Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir. 1994). However, the situation here is more subtle than TorPharm would make it out to be. The characteristic results from the testing methods that SmithKline seeks to use were not included in the language of the '723 patent. To

obtain any basis for comparison, SmithKline identified a compound matching all of the characteristics listed within the patent and then used that compound to obtain reference data with the new testing methods. To adopt TorPharm's argument that this process amounts to an unacceptable comparison of their compound to the commercial embodiment of the patent would allow them to escape the effect of our prior decision that SmithKline may employ testing methods not enumerated within the language of the patent. As stated above, we will not allow them to circumvent that ruling. However, their point is well taken that the reference materials, to be an acceptable basis for a point of comparison, must exhibit each and every one of the characteristics of the hemihydrate listed in the patent. With that caveat, we conclude that TorPharm's fifth motion in limine must be denied.

CONCLUSION

For the foregoing reasons, SmithKline's second and third motions in limine are granted. Their fourth motion in limine is denied. TorPharm's third motion in limine is granted. Their first is granted in part and denied in part, and the fifth is denied. All remaining motions in limine will be decided at time of trial.

Charles P. Kocoras

Charles P. Kocoras, Chief Judge
United States District Court

Dated: July 16, 2002